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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,225	03/26/2001	Peter Hawkins	109068	5800
25944	7590	04/05/2005	EXAMINER	
OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 04/05/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/816,225

Applicant(s)

HAWKINS ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Amendment entry and Claims Status**

The amendment filed on December 21, 2004 has been acknowledged and entered. Claims 9-13 are pending.

### ***Withdrawn Rejection (s)***

Rejection under 102 in the previous office action is withdrawn herein.

### ***New Ground(s) of Rejection***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A functional group or a binder conjugated to the magnetic particles in step (b) of claim 1 is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification of the present invention, on page 6, lines 5-10, discloses that the magnetic particles are bound to second molecules which bind with the layer of molecules on the substrate so as to bind the magnetic particles to the substrate". However, these second molecules are not recited in claim 1. These second molecules are critical to the present invention because they bind covalently to the monolayer of molecules on the substrate as to capture the magnetic labels. Covalent interaction is a stable binding interaction. Thus, the magnetic

particles bind to the molecules on the substrate through the second molecules would be stably captured on the substrate.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

*The nature of the invention:* - the instant invention is directed to a method of performing a binding assay by determining the number of magnetic particles bound to a substrate; the method comprising immobilizing a layer of molecules to a substrate, providing the magnetic particles as labels; performing a reaction using the molecular layer so as to bind at least some of the magnetic particles to the substrate; and determining the number of magnetic particles bound to the substrate by determining the difference in resonant frequency of a tuned circuit when the magnetic particles are exposed to a magnetic field generated by the tuned circuit.

The state of the art: - the prior art fails to teach a method of binding the magnetic particles (non-bound) as labels to the molecules of substrate.

The predictability or lack thereof in the art:- in view of the lack of teachings in the prior art that show or suggests that the magnetic particles can bind to the molecules on the substrate, the level of predictability is low.

The amount of direction or guidance present: - the instant specification fails to provide guidance on how to bind the magnetic particles directly to the molecules on the substrate without using any second binding molecules or functional groups that bind to the molecules on the substrate.

The presence or absence of working examples:- there is no examples in the specification that how to bind the magnetic particles directly to the molecules on the substrate without using any second binding molecules or functional groups that bind to the molecules on the substrate.

The quantity of experimentation necessary: - it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed since it is well known in the art that in order to attach a magnetic particle to a molecule on a substrate, binding between the magnetic particle and the molecule must occur directly through a functional group or indirectly through a second molecule that covalently binds to the molecule on the substrate.

The relative skill of those in the art: The level of skill in the art is high.

*The breadth of the claims:-* the claimed method is drawn to binding magnetic particles to a monolayer of molecules on a substrate and detecting the number of magnetic particles bound thereto by using a tuned circuit.

The specification, on page 6, lines 5-10, teaches that the magnetic particles can bind to the monolayer of molecules directly. However, it fails to teach an example of how the magnetic particles can bind to the monolayer of molecules since the magnetic particles do not possess any functional groups or attachment means that would bind to the monolayer of molecules. Such functional groups or attachment means are important because in order for the interaction of the magnetic particles and the molecules on the monolayer to be stable for detection, the magnetic particles must bind covalently or stably interact with the molecules on the monolayer to avoid dissociation of the interactions. Thus, functional groups are needed because the functional groups can stably interact with the functional groups on the molecules of the monolayer.

### ***Response to Arguments***

Applicant's arguments with respect to claims 9-13 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Claims 9-13 are free of prior arts.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
March 21, 2005

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 1641  
3/31/05